K000387

MAR - 2 2000

SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION PERTAINING TO SUBSTANTIAL EQUIVALENCE

A. Device Name

Proprietary Name

TERUMO® Needle with Locking Sheath or similar proprietary name

Classification Name

Hypodermic Single Lumen Needle (FMI) with sharps injury prevention device (locking sheath)
21CFR, Section 880.5570, Hypodermic Single Lumen Needle
Classification: Class II

Common Name

Hypodermic needle with locking sheath

B. Intended Use

The Terumo Needle with Locking Sheath is a device intended to inject fluids into, or withdraw fluids from, parts of the body below the surface of the skin. The device consists of a metal tube that is sharpened at one end and at the other end joined to a female connector (hub) designed to mate with a male connector (nozzle) of a piston syringe or an intravascular administration set. The device contains a locking sheath to be activated after needle use and prior to disposal to minimize the possibility of sharps injury.

C. Device Description

The Terumo Needle with Locking Sheath consists of a Needle and a Locking Sheath, which are assembled together.

The Needle is a device intended to inject fluids into, or withdraw fluids from, parts of the body below the surface of the skin. The device consists of a metal tube that is sharpened at one end and at the other end joined to a female connector (hub) designed to mate with a male connector (nozzle) of a piston syringe or an intravascular administration set.

The Locking Sheath is activated after needle use and prior to disposal to minimize the possibility of sharps injury. The locking sheath is activated with a one-hand operation by pressing the sheath against a hard surface, thereby engaging the needle into the sheath. An audible click indicates that the needle is firmly engaged within the sheath. The locking sheath is longer than the needle, to fully cover the entire needle. The Locking Sheath is compatible with luer-lock, slip tip and eccentric tip syringes, and with intravascular administration sets.

D. Substantial Equivalence

The Terumo Needle with Locking Sheath submitted in this 510(k) is substantially equivalent in intended use, design, technology/principles of operation, materials, and performance to the cleared the Terumo Needle (K771203), the SIMS Needle-Pro Needle Protection Device (K911037) and the SIMS Cartridge Needle-Pro, (K923127).

E. Principle of Operation and Technology

The Terumo Needle with Locking Sheath, the SIMS Needle-Pro and the SIMS Cartridge Needle-Pro are all operated manually.

F. Materials

The Terumo Needle with Locking Sheath uses the same materials as the Terumo Needle and the SIMS Needle-Pro. Differences in materials between the Needle with Locking Sheath and the SIMS Cartridge Needle-Pro, K923127, raise no new issues of safety and effectiveness.

G. Specifications

Product Code	Needle		Color of needle hub	Length of Locking Sheath
	Gauge	Length		
100425	21g	1-1/2"	Deep Green	2-1/4"
100424	22g	1-1/2"	Black	2-1/4"
100423	22g	1"	Black	1-5/8"
100422	23g	1"	Deep Blue	1-5/8"
100421	25g	5/8"	Orange	1-5/8"

H. Performance

The following performance tests were performed on the Needle with Locking Sheath:

- ANSI Taper
- Cannula Pull
- Protector Fit
- Hinge Flex
- Deadspace Volume
- Injection Leakage
- Aspiration Leakage
- Simulated Use

None of the data raises any new issues of safety and effectiveness. Additionally, a risk analysis was conducted and there were no new issues of safety and effectiveness.

The performance of the Needle with Locking Sheath is substantially equivalent to the performance of the Terumo Needle (K771203), the SIMS Needle-Pro (K911037) and the SIMS Cartridge Needle-Pro (K23127).

I. Additional Safety Information

Manufacturing controls include visual, functional, and sterility tests.

The sterility of the device is assured using a sterilization method validated in accordance with ANSI/AAMI/ISO 11135-1994 Medical Devices – Validation and Routine Control of Ethylene Oxide Sterilization, and EN550. The Terumo Needle with Locking Sheath is sterilized to provide a Sterility Assurance Level (SAL) of 10^{-6}.

Ethylene oxide residual levels resulting from EtO sterilization will not exceed the maximum residue levels proposed in the Federal Register Notice issued June 23, 1978, and indicated as follows:

Ethylene Oxide	25 ppm
Ethylene Chlorohydrin	25 ppm
Ethylene Glycol	250 ppm

The Needle with Locking Sheath is classified as Externally Communicating Device, Blood Path Indirect, Limited Duration of Contact (< 24 hr). The device's blood contacting materials were tested in accordance with the tests recommended in the FDA General Program Memorandum #G95-1 (5/1/95): Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part-1: Evaluation and Testing". Results of the testing demonstrate that the blood contacting materials are biocompatible.

Expiration dating for the Terumo Needle with Locking Sheath will be 12 months.

J. Conclusion

The Needle with Locking Sheath is substantially equivalent in intended use, design, technology / principles of operation, materials and performance to the Terumo Needle (K771203), the SIMS Needle-Pro (K911037) and the SIMS Cartridge Needle-Pro (K923127). Differences between the devices do not raise any significant issues of safety or effectiveness.

Terumo's statement of substantial equivalence is done solely to comply with the requirements of the Federal Food, Drug and Cosmetic Act and is not intended whatsoever to be the basis for a patent infringement action.

Date Prepared: February 3, 2000

Prepared By: Yuk-Ting Lewis
Senior Regulatory Specialist

Prepared For: Terumo Medical Corporation
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 2 2000

Ms. Yuk-Ting Lewis
Senior R.A. Specialist
Terumo Medical Corporation
Regulatory Affairs Department
125 Blue Ball Road
Elkton, Maryland 21921

Re: K000387
Trade Name: Terumo Needle with Locking Sheath
Regulatory Class: II
Product Code: FMI
Dated: February 1, 2000
Received: February 7, 2000

Dear Ms. Lewis:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of

the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4690. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K000387

510(k) Number (if known): _____

Device Name: Needle with Locking Sheath

Indications For Use:

The Terumo Needle with Locking Sheath is a device intended to inject fluids into, or withdraw fluids from, parts of the body below the surface of the skin. The device consists of a metal tube that is sharpened at one end and at the other end joined to a female connector (hub) designed to mate with a male connector (nozzle) of a piston syringe or an intravascular administration set. The device contains a locking sheath to be activated after needle use and prior to disposal to minimize the possibility of sharps injury.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

K000387

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number _____